K101670



# 510(k) Summary of Safety and Effectiveness

OCT - 8 2010

## Submission Information


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| **Company:** | United Orthopedic Corporation |
| **Address:** | No 57, Park Ave 2, Science Park, Hsinchu 300, Taiwan |
| **Contact Person:** | Fang-Yuan Ho,<br>Regulatory Affairs Manager<br>Phone:+886-3-5773351 ext. 212<br>Fax:+886-3-5777156 |
| **Date Prepared:** | June 11, 2010 |


## Device Identification

| | |
|---|---|
| **Device Name:** | U2 Bipolar Implant |
| **Common Name:** | Bipolar endoprosthesis |
| **Classification Name and Reference :** | Hip Joint femoral (Hemi-Hip) Metal/Polymer Cemented or Uncemented Prosthesis per 21CFR 888.3390. This falls under the Orthopedics panel. |
| **Predicate Device:** | 1. "UNITED" U1 Hip System – Bipolar (K050269)<br>2. "Wright" GLADIATOR Bipolar System (K062693) |

**Device Description:**

"UNITED" U2 Bipolar Implant, designed with a simple one-step assembly interface between femoral head and U2 Bipolar Implant, is a hemiarthroplasty design. U2 Bipolar Implant consists of an outer shell into which a bearing insert has been permanently assembled. The bearing insert has a factory assembled stopper ring and metal wire. The assembled prosthesis provides for primary articulation at the femoral

head/inner polyethylene bearing interface and secondary articulation at the outer shell/acetabulum interface. The internal aspect of the shell is designed to lock the polyethylene liner. The outer metal surfaces of the bipolar hip prosthesis are highly polished for articulation with the patient's acetabulum. Components are available in a range of sizes to fit varying anatomical requirements.

U2 Bipolar Implant are offered in 41-73 mm outer diameters and is designed to be used with either 26mm, 28mm, 32mm, or 36 mm femoral heads, depending on the inner diameter liner. The minimum thickness of the polyethylene at its thinnest point at a load bearing area of the liner is at lest 5.mm in U2 Bipolar Implant.

**Intended Use**

U2 Bipolar Implant is intended for use in combination with UNITED Femoral System for cemented or cementless hip replacement in skeletally mature patients with the following conditions: non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of function deformity; revision procedures where other treatments or devices have failed; treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

**Basis for Substantial Equivalence:**

The safety and effectiveness of U2 Bipolar Implant are substantially equivalent to the previously cleared U1 Hip System -- Bipolar (K050269), except for an extension in the size distribution and increasing stopper ring design. In addition, the subject device is also substantial equivalence to the "Wright" GLADIATOR Bipolar System (K062693).

These two devices both use a locking ring mechanism.

**Performance Test – Bench:**

The following tests were performed:

1. The integrity of locking mechanism
2. Range of motion evaluation

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

OCT 0 8 2010

United Orthopedic Corporation
% Ms. Fang-Yuan Ho
57 Park Ave
Science Park
Hsinchu, TW 300

Re: K101670
Trade/Device Name: U2 Bipolar Implant
Regulation Number: 21 CFR 888.3390
Regulation Name: Hip joint femoral (hemi-hip) metal/polymer cemented or uncemented
Regulatory Class: Class II
Product Code: KWY
Dated: October 4, 2010
Received: Oct0ber 7, 2010

Dear Ms. Ho:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

**510 (k) Number** (if known): K101670

**Device Name:** U2 Bipolar Implant

**Indications for Use:**

This device is intended for use in combination with UNITED Femoral System for cemented or cementless hip replacement in skeletally mature patients with the following conditions: non-inflammatory degenerative joint disease such as osteoarthritis, avascular necrosis, ankylosis, protrusio acetabuli, and painful hip dysplasia; inflammatory degenerative joint disease such as rheumatoid arthritis; correction of function deformity; revision procedures where other treatments or devices have failed; treatment of nonunion, femoral neck, and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques.

Prescription Use x AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Kaufman for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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